GE Healthcare

GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116

Certified Mail Return Receipt Requested

URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

August 12, 2008
FMI 15089

To: **Hospital Administrator**
Biomedical Engineers

Subject: **Product Safety Issues:**
X-ray beam alignment procedures for GE OEC 9900 Elite and GE OEC 9800 C-arms

Affected Products: **GE OEC 9900 Elite; GE OEC 9800 manufactured on or after June 10, 2006**

Our records indicate that your facility has one or more of the following GEHC OEC products:

- GE OEC 9900 Elite
- GE OEC 9800

GE Healthcare has found that our installation and periodic maintenance procedures for the GE OEC 9900 Elite and 9800 may not conform to federal regulations for proper beam alignment and overlap requirements in the Mag 1 or Mag 2 X-ray mode for system manufactured on or after June 10, 2006. The systems are compliant to the applicable regulations when operated in the Normal X-ray mode. This issue could result in less than 80% of the X-ray beam not overlapping the viewable area of the image receptor when Mag 1 or Mag 2 X-ray modes are used.

This issue does NOT pose a safety hazard as the system conforms to the X-ray beam regulations in effect prior to June 10, 2006. The revised procedure will assure compliance to the X-ray Beam regulations required on systems manufactured on or after June 10, 2006.

Solution:

Revised 9900 and 9800 Installation and Periodic Maintenance Procedures are included, and should be followed to assure proper beam alignment and X-ray beam overlap are within federal regulations.

A GEHC OEC Service Representative will assure proper beam compliance on your system on the next regularly scheduled Periodic Maintenance Interval, or will schedule a visit to your facility to address this issue.

If you have any questions or concerns regarding this issue, please do not hesitate to contact the service team for further information at 800-874-7378 option #8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
President and CEO

Maria Frame
Vice President Quality and Regulatory Affairs